REMARKS

Claim Rejections - 35 USC §103

Claims 1-5, 7-19, 23-24 and 26 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Daly (U.S. 2004/0186444) in view of Twyman (U.S. 2,755,060). This rejection is respectfully traversed.

At page 2 of the Official Action, the Examiner cites Daly for its disclosure of "a valve apparatus ... that includes two lumens ... with two valves ... wherein the valves are biased in the closed configuration and configured to open at a predetermined pressure." The Examiner concedes that Daly fails to disclose "the inclusion of biasing members coupled to the valves in order to further bias the valves in the closed position," as required by the rejected claims. Applicants agree.

In an effort to overcome this deficiency, the Examiner cites Twyman, for its purported teaching of "a valve member (14) which includes a slit (16) that is biased in a closed configuration and further includes a biasing member (18) coupled to the valve member that further biases the slit in the closed configuration." *Official Action at 2.*

The Examiner states that Twyman discloses a "first flexible disk including a plurality of first movable elements formed on opposite sides of at least one first slit extending through the first flexible disk, wherein a size and configuration of the first slit is selected to provide desired opening and closing characteristics of the moveable elements," as is recited in instant claim 1. Applicants respectfully disagree. Twyman does not disclose a flexible disc. Instead, Twyman discloses a convex valve structure. *See,* Col. 1, lines 70-72 ("The tube 10 is provided with a transverse flexible wall *which is convex (preferably but not necessarily spheroidal) on its right-hand or upstream side.*"). This structure may be oblate (Fig. 3) or prolate (Fig. 4). The convex structure of the Twyman valve is taught by Twyman to be critical to its function. *See* Col. 2, lines 5-10 ("The curvature and thickness of the wall 14 are chosen so that (at least, when reinforced as described below), it is self-supporting against the fluid pressure on the upstream or right-hand side of the wall and is sufficiently resilient to assume the closed position of Figs. 1, 2, and 3 even in the absence of such upstream pressure."). However, in no instance does Twyman disclose a flexible *disc* of any kind.

Moreover, as noted above, the convex valve structure of Twyman *requires* the presence of a "reinforcing and slit-controlling member" in order to carry out its functions. In contrast, the flexible disc of Daly does not require the presence of a "reinforcing and slit-controlling member." Instead, Daly employs rigid "diaphragm securement members 197 and 199" that serve to support the slit valves. Accordingly, one of ordinary skill in the art would simply have no reason

to modify the valves of Daly with the reinforcing members of Twyman. The mere fact that references *can* be combined, without more, does not render the resultant combination obvious. *KSR v. Teleflex,* 82 USPQ2d 1385, 1396 (Fed. Cir. 2007).

Finally, the valves of the Daly assembly permit fluid flow in either direction when sufficient pressure is applied. *See, e.g.,* Daly, paragraph [005] ("allow the first fluid to flow in the desired direction ... allow the second fluid to flow in the desired direction."). Thus incorporating a convex valve structure as shown in Twyman into the valve assembly of Daly would prevent the Daly assembly from functioning as designed. If the proposed modification or combination of the prior art would change the principle of operation of the prior art invention being modified, then the teachings of the references are not sufficient to render the claims *prima facie* obvious. *In re Ratti,* 123 USPQ 349 (CCPA 1959).

For the foregoing reasons, the instant claims are not *prima facie* obvious over Daly in view of Twyman. Accordingly, withdrawal of this rejection is respectfully requested.

Claims 15-17 and 23-26 stand rejected under 35 USC 103 as purportedly obvious over Smith (U.S. Patent No. 4,244,379) in view of Twyman. This rejection is respectfully traversed.

The Examiner asserts, at page 3 of the Official Action, that Smith "discloses most of the limitations recited in the claims above, but fails to explicitly teach a biasing element coupled to the flexible disk adjacent to the first slit to urge the moveable elements towards the closed position as is now recited." Applicants agree that Smith does not disclose all of the elements of the rejected claims. However, the deficiencies of Smith are not remedied by the teachings of Twyman.

The deficiencies of Twyman are discussed in detail above. In no instance does Twyman disclose a flexible *disk* of any kind. Moreover, as noted above, the convex valve structure of Twyman *requires* the presence of a "reinforcing and slit-controlling member" in order to carry out its functions. In contrast, the flexible disk of Smith does not require the presence of a "reinforcing and slit-controlling member." Accordingly, one of ordinary skill in the art would simply have no reason to modify the valve of Smith with the reinforcing members of Twyman. The mere fact that references *can* be combined, without more, does not render the resultant combination obvious. *KSR v. Teleflex,* 82 USPQ2d 1385, 1396 (Fed. Cir. 2007).

There is an additional important difference between the teachings of Twyman and Smith that would lead one of ordinary skill in the art away from combining the teachings of the two patents. The slit in the Twyman valve bisects the convex valve along its circumference. The valve assembly of Smith incorporates a flexible disk that is also provided with a slit. However,

the slit does not bisect the disk along its diameter, as it would if it matched the slit of Twyman. Instead, in Smith the slit is short, and is "positioned eccentrically with regard to the center of the disk valve member 130, as is shown in Fig. 3." The use of an eccentric slit is taught by Smith to be important for the functioning of the valve; when reverse pressure is applied to the valve, "the valve member 103 is merely forced against the backing disk 140, and the slit 132 does not open thereby preventing any fluid flow in the incorrect direction." *See Col. 5, lines 48-53.* One of ordinary skill in the art would not be motivated to modify the valve of Smith with a reinforced slit as disclosed by Twyman, because the circumferential slit of Twyman would not provide the advantages of the eccentric slit of Smith in the Smith valve assembly.

For the foregoing reasons, the instant claims are not *prima facie* obvious over Smith in view of Twyman. Accordingly, withdrawal of this rejection is respectfully requested.

Claims 18-19 stand rejected under 35 USC 103 as purportedly obvious over Smith (U.S. Patent No. 4,244,379) in view of Twyman and further in view of Jones (U.S. Patent No. 2,720,881). This rejection is respectfully traversed.

The deficiencies of Smith and Twyman are discussed in detail above. These deficiencies are not remedied by the disclosure of Jones. The Examiner concedes that Smith and Twyman "do not disclose a pair of second perpendicular slits interesting the first slit." However, the Examiner asserts that "Jones teaches such a configuration and teaches that this configuration is useful in pressure actuated valves." Applicants respectfully disagree with this characterization of the teachings of Jones. Jones does not teach a valve. Jones teaches, in one embodiment, a paper medicament dispenser that is covered by a cap 14 that incorporates flaps 16. The medicament dispenser of Jones is a single-use device. In contrast, the valves of the present claims are designed to open and close repeatedly. One of ordinary skill in the art would not be motivated to modify the device of Smith with a single-use cap according to Jones to arrive at the presently claimed invention.

For the foregoing reasons, the instant claims are not *prima facie* obvious over Smith in view of Jones and Twyman. Accordingly, withdrawal of this rejection is respectfully requested.

CONCLUSION

From the foregoing, further and favorable action in the form of a Notice of Allowance is believed to be next in order and such action is earnestly solicited.

In the event that there are any questions relating to this Amendment or to the application in general, the Examiner is respectfully urged to telephone Applicants' undersigned representative so that prosecution of the application may be expedited.

The Director is hereby authorized to charge any additional fees which may be required, or credit any overpayment to Deposit Account No. 50-4047 (7062172001).

Respectfully submitted,

BINGHAM MCCUTCHEN, LLP

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By: _____
Malcolm K. McGowan, Ph.D.
Registration No. 39,300

BINGHAM MCCUTCHEN, LLP
2020 K Street, NW
Washington, DC 20006
Telephone: (202) 373-6000
Facsimile: (202) 373-6001